

NATURAL HEALTH PRODUCT

DONG QUAI – *ANGELICA SINENSIS*

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient.

Notes

- Products making any Traditional Chinese Medicine (TCM) claim must be prepared according to the most recent version of the Chinese Pharmacopoeia (e.g. identification criteria, processing methods, methods of preparation).
- Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant's discretion.
- The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant.

Date

July 26, 2024

Proper name(s), Common name(s), Source information

Table 1. Proper name(s), Common name(s), Source information

Proper name(s)	Common name(s)	Source information		
		Source material(s)	Part(s)	Preparation(s)
<i>Angelica sinensis</i>	<ul style="list-style-type: none"> • Chinese angelica • Dang quai • Dang qui • Dong gui • Dong quai • Tang-kuei 	<i>Angelica sinensis</i>	Root	Dry

References: Proper name: USDA 2023; Gardner and McGuffin 2013; Common names: USDA 2023; NS 2021; PPRC 2020; Gardner and McGuffin 2013; derMarderosian and Beutler 2010; Bensky et al. 2004; Chen and Chen 2004; Source information: PPRC 2020; Bensky et al. 2004; Chen and Chen 2004.

Route of administration

Oral

Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.

Use(s) or Purpose(s)

- Used in Traditional Chinese Medicine (TCM) to invigorate and tonify the blood (PPRC 2020; Bensky et al. 2004; Chen and Chen 2004).
- Used in Traditional Chinese Medicine (TCM) to harmonize the blood (Bensky et al. 2004).

Notes

For multi-ingredient products:

- To prevent the product from being represented as a "traditional medicine", any indicated traditional use claim must refer to the specific medicinal ingredient(s) and recognized traditional system of medicine from which the claim originates when 1) both traditional and modern claims are present or 2) when claims originate from multiple systems of traditional medicine (e.g. Dong quai is used in Traditional Chinese medicine to invigorate and tonify the blood).
- When ALL of the medicinal ingredients (MIs) in the product are used within the SAME identified system of traditional medicine AND the product makes ONLY traditional claims, listing of MIs in the traditional claim(s) is not required

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Methods or preparation: Dry, Powdered, Non-Standardized Extracts (Dry extract*, Tincture, Fluid extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate)

4.5 - 15 grams of dried root, per day (PPRC 2020; Bensky et al. 2004; Chen and Chen 2004).

Notes:

- The root may also be 'prepared' as per the specific TCM methods of preparation for Dong quai root described in TCM reference texts (e.g. dry-fried; stir-baked or dry-fried with wine/grain based liquor/vinegar; charred; etc.) (PPRC 2020; Bensky et al. 2004; Chen and Chen 2004).
- *Solvents allowed for the method of preparation "Non-standardized extracts (Dry extract)" as part of this monograph are ethanol and/or water only.

Direction(s) for use

No statement required.

Duration(s) of use

Ask a healthcare practitioner/health care provider/health care professional/doctor/physician for use beyond 6 months (Hirata et al. 1997).

Risk information

Caution(s) and warning(s)

- **Ask a healthcare practitioner/health care provider/health care professional/doctor/physician before use** if you are breastfeeding (NS 2021).
- **Ask a health care practitioner/health care provider/health care professional/doctor/physician prior to use** if you are taking any medications including blood thinners, birth control pills or hormone therapy (NS 2021; Brinker 2010; WHO 2002).
- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before use** if you have serious or major conditions, any type of acute infection, deficiency or excess (HC 2022).
- **When using this product** avoid exposure to the sun (NS 2021; Thorne 2004).

Contraindication(s)

- **Do not use** if you are pregnant (NS 2021; WHO 2002).
- **Do not use** if you have diarrhea, hemorrhagic diseases or heavy periods (NS 2021, Bensky et al. 2004; Chen and Chen 2004; WHO 2002).

Known adverse reaction(s)

Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen, or if new symptoms develop such as breast pain or any changes in menstrual cycles (Brinker 2010; Schumacher et al. 2007; Thorne 2004; Russell et al. 2002).

Non-medicinal ingredients

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

Storage conditions

Must be established in accordance with the requirements described in the *Natural Health Products Regulations*.

Specifications

- The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide. Note that if the ingredient is prepared according to the most recent version of the Chinese Pharmacopoeia, the quality requirements must meet or exceed those described in the NNHPD Quality Guidance.
- The medicinal ingredient must comply with the requirements outlined in the NHPID.

EXAMPLE OF PRODUCT FACTS:

Consult the Guidance Document, [Labelling of Natural Health Products](#) for more details.

Product Facts
Medicinal ingredient in each capsule <i>Angelica sinensis</i> (Dong quai) (X:1 extract) XX mg Equivalent to XX g of dried root
Uses <ul style="list-style-type: none"> Used in Traditional Chinese Medicine (TCM) to invigorate and tonify the blood. Used in TCM to harmonize the blood.
Warnings
If applicable¹: Allergens: food allergen, gluten (gluten source), sulphites Contains aspartame
Do not use if • you are pregnant • you have diarrhea, hemorrhagic diseases or heavy periods.
Ask a health care practitioner before use if • you are breastfeeding • you are taking any medications including blood thinners, birth control pills or hormone therapy • you have serious or major conditions, any type of acute infection, deficiency or excess.
When using this product avoid exposure to the sun.
Stop use and ask a health care practitioner if symptoms persist or worsen, or if new symptoms develop such as breast pain or any changes in menstrual cycles.
Directions Adults 18 years and older: • Take X dose(s), X time(s) per day • Ask a health care practitioner for use beyond 6 months.
Other information (Add storage information)
Non-medicinal ingredients List all NMIs
Questions? (Call) 1-XXX-XXX-XXXX

¹This section can be removed from the table if the product contains no allergen or aspartame.

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